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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/853,526 | 08/27/2001 | Daniel Cohen | GEN-T111XC3D1 | 7147 |

7590 06/16/2004

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EXAMINER

YAEN, CHRISTOPHER H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/853,526 | Applicant(s) COHEN ET AL. | |
| | Examiner Christopher H Yaen | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Re: Cohen *et al*

Priority Date: 22 December 1997

1. The amendment filed 5/1/2004 is acknowledged and entered into the record. Accordingly, claims 1-49 are canceled without prejudice or disclaimer, and claims 63-65 are newly added.
2. Claims 50-65 are therefore pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 101

3. The rejection of claims 50-61 and now claims 62-65 under 35 USC 101 as lacking a credible, substantial, and specific utility is maintained for the reasons of record. The rejection under 35 USC 112, 1st paragraph as lacking an enabling disclosure, specifically because the specification has not set forth a specific or substantial utility is also maintained. Applicant argues that the instantly claimed PG1 is associated with prostate cancer, and submits that US Patent 6,346,381 teaches the analysis and association of the PG1 gene with prostate cancer. Applicant further argues that different isoforms exist within a cell and that the detection of the different isoforms of PG1 would provide for a means to diagnose tumorigenic tissue. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Association alone is insufficient evidence that a substantial real world use has been associated with the protein. Since the instantly claimed invention is drawn to a method of detecting the PG1 protein with an anti-PG1 antibody, it must logically flow that the PG1 protein must have a specifically or

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substantially asserted utility. However, such is not the case. The specification aside from providing analysis of the expression and location of the PG1 protein has not set forth a utility that is well known, immediately apparent, or implied from the specification. The assertion that the utility of the instant invention is for the purification of a PG1 protein is not considered substantial because any antibody will bind to a specific antigen, and applies to a broad class of antibodies. This does not constitute a real world use for the antibody, nor does it provide a substantial use for the PG1 protein. In other words, other than simply binding, what will the skilled artisan do with the antibody if there has been no associated biological activity associated with the protein? Further once the protein has been detected or bound to the antibody, what does this mean in terms of real world applicability? Neither the art nor the specification has adequately described the activity of the PG1 protein, and thereby the binding of an antibody to the PG1 protein does not provide any applicability other than binding. It does not provide any insight into a particular disease or disorder.

Moreover, the detection of PG1 isoforms has not been specifically correlated to the presence of prostate cancer. The applicant only assert that other protein isoforms or splice variants and gene products are associated with other types of cancers, but has not specifically provided evidence that such splice variants are indicative of prostate cancer. The use of information regarding another protein isoforms does not appropriately correlate to the instantly taught PG-1 protein and therefore the detection of such PG-1 isoforms does not specifically teach a substantial or specific utility. For

the reasons set forth above, the rejection under 35 USC 101 and 112, 1st paragraph as lacking a specific and substantial utility is maintained.

Claim Rejections Maintained - 35 USC § 112, 1st paragraph

4. The rejection of claims 50-61 and now claims 63-65 under 35 USC 112, 1st paragraph as lacking proper written description is maintained for the reasons of record. Applicant argues that numerous species of cDNA are presented in the specification and further states that the specification teaches a variety of polypeptides that are derived from the cDNA species of which are isoforms. Applicant concludes that the specification provides adequate teaching of peptides or amino acids that fall within the scope of the invention because a representative number of species has been taught. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. Contrary to what applicant has stated, the claims are drawn to any amino acids sequence provided that there are 8 contiguous amino acids from any of SEQ ID No: 4,5 and 70. The species taught in the specification do not adequately teach one of skill in the art a representative number of sequences because there are sequences within the different SEQ ID numbers of which are not listed nor contemplated at the time of filing. The specification does not specifically teach any associated functional activity with all possible sequences derived from the SEQ ID numbers, nor are there any specific core structure or attribute that would help one of skill in the art distinguish the claimed sequences from any another 8 amino acid sequence. No structures, chemical properties, or common attributes have been

provided and therefore one of skill in the art cannot sufficiently determine whether the applicant was in possession of all amino acids of which is at least 8 amino acids in length from others in the protein class which is highly variable. One of skill in the art cannot readily screen for peptides that are at least 8 amino acids in length because there is not functional activity associated. Therefore, the reliance on SEQ ID No: 4,5 and 70 alone is insufficient to adequately describe all possible amino acids found within the said sequences. The disclosure of isoforms derived from SEQ ID No: 4,5,and 70 is also insufficient because those sequences are not representative of the genus of peptides claimed, because there is not distinguishing feature taught in the sequences. Thus applicant was not in possession of all possible species to be entitled to the genus claimed. Therefore the rejection under 35 USC 112, 1st paragraph is maintained.

Conclusion

5. No claim is allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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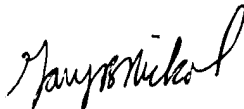
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
June 10, 2004



GARY NICKOL
PRIMARY EXAMINER